Trial record **1 of 5** for: "kang zhang"

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Clinical Assessment Of Age-related Macular Degeneration Patients After Early Diagnosis and Treatment With Ranibizumab (COMPASS)

ClinicalTrials.gov Identifier: NCT01402544

Recruitment Status : Terminated (Per study sponsor decision.)
First Posted : July 26, 2011
Last Update Posted : July 18, 2016

Sponsor:
Kang Zhang, MD, PhD

Collaborator:
Genentech, Inc.

Information provided by (Responsible Party):
Kang Zhang, MD, PhD, University of California, San Diego

Study Details | Tabular View | No Results Posted | Disclaimer

How to Read a Study Record

Study Description

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Brief Summary:

To determine if patients treated early after diagnosis of wet age-related macular degeneration can return/maintain to their baseline pre-disease BCVA.

Condition or disease	Intervention/treatment	Phase
Age-Related Macular Degeneration	Drug: ranibizumab	Phase 2 Phase 3

Detailed Description:

We will conduct an open label, multi-center study of naïve AMD patients that are identified early upon disease progression (had a normal VA, FA or OCT within 4 months prior to entry) to assess if treating with ranibizumab monthly can restore all patients to their baseline vision pre-AMD. Recent randomized clinical trials (MARINA, ANCHOR) have conclusively demonstrated that continued intravitreal therapy with ranibizumab in patients with subfoveal CNV from AMD leads to stabilization of vision in over 90% of patients and improvement in vision in at least a third of the patients and has led to the approval of ranibizumab (0.5 mg) for the treatment of neovascular AMD.

Patients will receive monthly intravitreal ranibizumab injections for 12 months (with dose holding for return to baseline/ 20/20 or better and no evidence of fluid on SD-OCT or FA). All patients will have ETDRS vision and SD-OCT, and complete exam at each monthly visit. Patients will each have a blood analysis for genetics (either during the GALLEY study in which they converted to wet AMD and entered COMPASS or during this study).

Study Design

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Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	20 participants
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment

Official Title:	Clinical Assessment Of Age-related Macular Degeneration Patients After Early Diagnosis and Treatment With Ranibizumab (COMPASS)
Study Start Date :	July 2011
Actual Primary Completion Date :	March 2015
Actual Study Completion Date :	March 2015

Resource links provided by the National Library of Medicine NIH NLM

Genetics Home Reference related topics: Age-related macular degeneration

MedlinePlus related topics: Macular Degeneration

Drug Information available for: Ranibizumab

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Ranibizumab 0.5 mg Ranibizumab 0.5 mg Intravitreal Injection, monthly, open-label, for the duration of 1 year	Drug: ranibizumab 0.5mg intravitreal injection, monthly for 12 months, or until BCVA returns to pre-wet AMD baseline. Other Name: Lucentis

Outcome Measures

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Primary Outcome Measures :

1. Pre-wet AMD baseline visual acuity [Time Frame: Monthly for 12 months]

% of patients that achieve their pre-wet AMD baseline vision within 12 months

Secondary Outcome Measures :

1. Mean change in BCVA at 6 and 12 months [Time Frame: Month 6 and Month 12 in 12-month time frame]

   Mean change in BCVA at 6 and 12 months

2. Mean change in CFT at 6 and 12 months [Time Frame: Month 6 and Month 12 in 12-month study time frame]

   Mean change in CFT at 6 and 12 months

3. Genome variations contributing to onset, progression and severity of CNV.
   [Time Frame: End of 12-month study time frame]

   Genome variations contribution/prediction to onset, progression and severity of CNV (lesion size and BCVA), the efficacy of treatment relative to gene status.

Eligibility Criteria Go to

Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	50 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Ability to provide written informed consent and comply with study assessments for the full duration of the study
- Age > 50 years
- Naïve wet-AMD within 4 months of disease onset (for GALLEY patients) and within 3 months of disease onset for all others
- Patients that have lost > 5 letters from baseline best vision
- BCVA 20/25-20/320

Exclusion Criteria:

- Pregnancy (positive pregnancy test) or lactation
- Premenopausal women not using adequate contraception. The following are considered effective means of contraception: surgical sterilization or use of oral contraceptives, barrier contraception with either a condom or diaphragm in conjunction with spermicidal gel, an IUD, or contraceptive hormone implant or patch.
- Any other condition that the investigator believes would pose a significant hazard to the subject if the investigational therapy were initiated
- Participation in another simultaneous medical investigation or trial which includes an intervention (Patients could be participating in a non-interventional study such as the GALLEY study)
- Juxtafoveal and extrafoveal wet-AMD

Contacts and Locations

Go to

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT01402544***

Locations

United States, California

California Retina Consultants
Bakersfield, California, United States, 93309

Shiley Eye Center, UCSD
La Jolla, California, United States, 92093

California Retina Consultants
Santa Barbara, California, United States, 93103

United States, Texas

Medical Center Ophthalmology Associates
San Antonio, Texas, United States, 78240

Sponsors and Collaborators

Kang Zhang, MD, PhD

Genentech, Inc.

Investigators

Principal Investigator: **Kang Zhang**, MD, PhD University of California, San Diego

More Information

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Additional Information:

Related Info EXIT

Responsible Party:	**Kang Zhang**, MD, PhD, Professor of Ophthalmology and Human Genetics, University of California, San Diego
ClinicalTrials.gov Identifier:	NCT01402544 History of Changes
Other Study ID Numbers:	110567
First Posted:	July 26, 2011 Key Record Dates
Last Update Posted:	July 18, 2016
Last Verified:	July 2016

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Keywords provided by **Kang Zhang**, MD, PhD, University of California, San Diego:

AMD
Choroidal neovascularization
Ranibizumab
Age-related Macular Degeneration
Genome

Additional relevant MeSH terms:

Macular Degeneration
Retinal Degeneration
Retinal Diseases
Eye Diseases
Ranibizumab
Angiogenesis Inhibitors
Angiogenesis Modulating Agents
Growth Substances
Physiological Effects of Drugs
Growth Inhibitors
Antineoplastic Agents